FDA and Health Behavior Regulation
Food and Drug Law Journal 2017 Symposium
Speaker Biographies

STEVEN ARMSTRONG is an independent advisor at EAS Consulting Group. He has over 20 years of experience advising leading consumer products companies on marketing and regulatory matters. Prior to EAS, Mr. Armstrong served as the Chief Food Law Counsel at Campbell Soup Company, where he counseled Campbell businesses on food safety, food policy, labeling, and regulatory compliance, including matters involving FDA, USDA and food agencies around the world. He has also served as the Senior Marketing Counsel at Energizer's Schick-Wilkinson Sword Division and as the Assistant General Counsel for Marketing at Unilever United States. Mr. Armstrong is on the Board of Directors of the Food and Drug Law Institute, and is a frequent speaker on food law issues. Mr. Armstrong earned his bachelor's degree from Harvard College and his law degree from Columbia University.

FREDERICK R. BALL is a Partner at the law firm of Duane Morris LLP. He is vice-chair of Duane Morris's White-Collar Government Regulatory Division of the Trial Practice Group and heads its Pharmaceutical, Pharmacy and Food Group. He focuses his practice on assisting companies or individuals when they are adverse to state or federal governments, including administrative, civil, and criminal matters with FDA, DEA, CMS, and other federal and state regulatory agencies. Mr. Ball helps generic pharmaceutical companies, biologics manufacturers, food companies (including supplement manufacturers), pharmacies, long-term care providers, and other health care providers navigate the complex challenges faced by state and federal regulation of their industries, including complying with current Good Manufacturing Practices, price reporting (AMP, AWP, ASP, etc.), the Foreign Corrupt Practices Act, and fraud and abuse laws including labeling and advertising requirements. Mr. Ball also assists generic manufacturers bring products to market through patent analysis and Hatch-Waxman litigation. He serves on the FDLI Board of Directors, and is admitted to the Illinois State Bar, the Seventh Circuit, and the U.S. Supreme Court. A member of the American and Illinois State bar associations, Mr. Ball is a 1996 cum laude graduate of Cornell Law School and a graduate of the University of Colorado at Boulder.

JEFF CHASNOW is Senior Vice President and Associate General Counsel at Pfizer Inc, and Chief Counsel for Pfizer Innovative Health. Prior to joining Pfizer in 1999, Jeff was a trial attorney at the Department of Justice's Office of Consumer Litigation (now called the Consumer Protection Branch), where he litigated numerous cases addressing the legality of FDA regulatory actions. At FDLI, Jeff has served on the H. Thomas Austern Writing Awards Committee (including as chair) and the editorial advisory board of the FDLJ (including as chair). Jeff also has taught food and drug law as an adjunct faculty member at the Temple University School of Pharmacy and as a guest lecturer at the Fordham and Quinnipiac law schools. Jeff presented at FDLJ's 2015 symposium, "Constitutional Challenges to the Regulation of Food, Drugs, Medical Devices, Cosmetics, and Tobacco Products," on the topic "Preemption of Non-Federal Restraints on Off-Label Product Communications." His article on that topic, co-authored with Geoffrey Levitt, is available at 71 Food and Drug L. J. 249 (2016).

KELLIE COMBS is a partner in the Life Sciences group at Ropes & Gray LLP, where she provides legal and strategic advice to pharmaceutical, biotechnology, and medical device manufacturers on a broad range of issues under the Food, Drug, and Cosmetic Act, and the Public Health Service Act. She serves as co-counsel to the Medical Information Working Group, represented Pacira in its litigation against FDA, and has

extensive experience handling matters implicating FDA promotional rules and the First Amendment. Kellie also routinely advises clients on lifecycle management, regulation of clinical research, and post-approval compliance. In addition, she conducts regulatory due diligence in connection with transactions involving life sciences clients, and advises on government investigations of FDA-regulated companies.

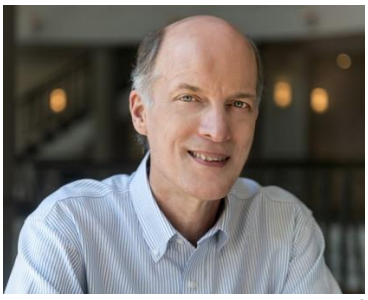
JOHN A. GILBERT, Jr. is a director at the law firm of Hyman, Phelps & McNamara, PC in Washington, DC. The firm advises and represents a broad range of clients on legal issues concerning food, drug, medical devices, biologicals, pharmacy, and cosmetic law and regulation. Mr. Gilbert has advised clients extensively on legal and regulatory issues concerning controlled substances, prescription drugs, and precursor chemicals. He advises on federal and state laws and regulations governing the scheduling, manufacturing, distribution, dispensing, import, and export of prescription drugs, controlled substances, and regulated chemicals. He has represented clients before the Drug Enforcement Administration (DEA) and handled numerous litigation matters involving civil and administrative actions related to violations of the federal Controlled Substances Act (CSA) and state laws. Mr. Gilbert also has extensive experience in scheduling and regulation of controlled substances under the international drug control treaties and issues related to the United Nations Drug Control Program. He has also advised and represented clients on matters related to the World Health Organization's Expert Committee on Drug Control. Prior to joining the firm in 1995, Mr. Gilbert was an attorney in the DEA's Office of Chief Counsel, Diversion/Regulatory Section. He also served as a law clerk in the DEA Office of Administrative Law Judges as part of the Department of Justice Honor's Program. He is admitted to practice law in the District of Columbia and Virginia, and is a member of the American Bar Association and of the Administrative Law and Health Law sections of the Virginia State Bar. Mr. Gilbert received a BA in Political Science from Westfield State College and his law degree from the Catholic University of America, where he was an associate editor of the *Catholic University Law Review*.

PETER BARTON HUTT is Senior Counsel in the Washington, DC law firm of Covington & Burling LLP specializing in food and drug law. He teaches a full course on food and drug law at Harvard Law School during winter term. He served as Chief Counsel for the Food and Drug Administration (FDA) from 1971 to 1975. Mr. Hutt is the co-author of the casebook used to teach food and drug law throughout the country, and has published numerous book chapters and articles on food and drug law and health policy. He has been a member of the Institute of Medicine (now the National Academy of Medicine) since it was founded in 1971 and serves on a wide variety of academic and scientific advisory boards and on the Board of Directors of venture capital startup companies. He served on the Administrative Restructuring of the National Institutes of Health (NIH) and the Working Group to Review Regulatory Activities Within the Division of AIDS of the National Institute of Allergy and Infectious Diseases and was a consultant to the FDA Science Board Subcommittee to review the agency's science needs to perform its regulatory mission. Mr. Hutt has been referred to in various publications as one of the best food and drug lawyers over the years. He was named by *The Washingtonian* magazine as one of Washington's 50 best lawyers and as one of Washington's 100 most influential people, by the *National Law Journal* as one of the 40 best healthcare lawyers in the United States, and by *European Counsel* as the best FDA regulatory specialist in Washington, DC. In 2005, he was presented the FDA Distinguished Alumni Award by the agency and the Foundation for Biomedical Research gave him the Lifetime Achievement Award for research advocacy. In 2007, the FDA Alumni Association gave him the Harvey W. Wiley Award for significant lifetime

contribution to the mission of FDA. Mr. Hutt received his BA *magna cum laude* from Yale University, his LLB from Harvard University, and his LLM from New York University.

DEEPTI KULKARNI is an associate in the Food, Drug and Medical Device Regulatory practice at Sidley Austin LLP, where she counsels clients on a wide range of matters involving FDA regulatory issues. Deepti focuses her practice on assisting clients in launching their products and complying with regulations for foods and dietary supplements, animal products, medical devices, and prescription and OTC drugs. In addition, she counsels clients on potential crises, such as product recalls, import refusals, and other regulatory actions. Prior to joining Sidley, Deepti served as an Associate Chief Counsel in the FDA's Office of Chief Counsel from 2009 to 2015. While at FDA, Deepti counseled various components of FDA and HHS on a broad scope of issues related to conventional foods, dietary supplements, and animal products, as well as cross-product matters involving advisory committees, imports/exports, and constitutional issues. Deepti received several individual and group awards during her time at the FDA, including the FDA Award of Merit (FDA's highest award), Commissioner's Special Citation, Commissioner's Special Recognition Award, and the CFSAN Director's Special Citation Award.

GEOFFREY M. LEVITT is Senior Vice President and Associate General Counsel for Regulatory, Environmental, and Global Supply at Pfizer Inc, where he is responsible for managing global legal support for regulatory, medical, safety, clinical research, manufacturing, and environmental operations. Mr. Levitt has published and lectured extensively on regulatory law. He is a past member of the editorial board of the *Food and Drug Law Journal* and a current member of the editorial board of the *FDA Advertising and Promotion Manual*. Mr. Levitt is past Chairman of the Board of the Food and Drug Law Institute and received the Institute's 2009 Distinguished Service and Leadership Award and the 2017 inaugural Service to FDLI Award. He has also served as Chair of the PhRMA Law Section Executive Committee and is a current member of the Board of the Friedreich's Ataxia Research Alliance. He earned his JD from Harvard Law School and his BA from Columbia University.



ERIC LINDBLOM is Director for Tobacco Control and Food & Drug Law at Georgetown Law's O'Neill Institute for National and Global Health Law. He works on a range of law and policy projects relating to U.S. and global tobacco control efforts, FDA regulation, the First Amendment, legalized cannabis, and other domestic and international regulatory matters. Before joining the O'Neill Institute, Mr. Lindblom was Director of the Office of Policy at the FDA Center for Tobacco Products. Prior to that, Mr. Lindblom served as General Counsel and Director for Policy Research at the Campaign for Tobacco-Free Kids, and previously held positions with the federal government, a member of Congress, political campaigns, a law firm, and nonprofit advocacy organizations. Mr. Lindblom has a JD from Harvard Law School and a BA in Political Science from Yale University.

MATTHEW MYERS is President of the Campaign for Tobacco-Free Kids, a leader in the fight to reduce tobacco use in the United States and around the world. Myers has

been involved in virtually every major national legislative effort over the last 30 years, including the successful effort that led Congress in 2009 to give FDA jurisdiction over tobacco products. Under his leadership the Campaign for Tobacco-Free Kids was selected by Bloomberg Philanthropies in 2006 as one of the lead participants in the Bloomberg Initiative to Reduce Tobacco Use in Low and Middle Income Countries.

JOSEPH A. PAGE is a professor emeritus at Georgetown University Law Center, where he taught torts, products liability, and food and drug regulation. He has contributed chapters on the regulation of tobacco products for the third edition of *Food and Drug Law and Regulation* and for the sixth edition of *A Practical Guide to FDA's Food and Drug Law and Regulation*. He is currently the faculty advisor for the Georgetown Law student editors of the *Food and Drug Law Journal*. Professor Page also writes about Latin America, and has published books entitled *Perón: A Biography* and *The Brazilians*.

EFTHIMIOS PARASIDIS is Associate Professor of Law and Public Health at Ohio State University, and Faculty Affiliate at OSU's Center for Bioethics and Medical Humanities. He has published extensively on topics in health law, public health, and bioethics, with a focus on FDA law and policy. He currently serves as a law and bioethics consultant for the U.S. Air Force, and the Greenwall Foundation awarded Professor Parasidis a Faculty Scholar in Bioethics fellowship for 2014-2017. Professor Parasidis served as an Assistant Attorney General for the State of New York, under Eliot Spitzer and Andrew Cuomo; in private practice, he was an associate in the Litigation group of Jones Day and a senior associate in the Intellectual Property group of Dickstein Shapiro. Professor Parasidis counsels start-up companies, is co-founder of a biotechnology start-up company, and is a co-inventor on a patent application related to health information technology.

AMY COMSTOCK RICK is President and Chief Executive Officer of the Food and Drug Law Institute, having joined in August 2014. Prior to joining FDLI, Ms. Rick was the Chief Executive Officer of the Parkinson's Action Network (PAN) from 2003-2014. PAN is a Washington DC-based national nonprofit focused on educating the public and government leaders on better policies for research and therapy development and an improved quality of life for people living with Parkinson's disease. Ms. Rick has also served as the President of the Coalition for the Advancement of Medical Research, on the Boards of Directors of Research!America, the National Health Council, and the American Brain Coalition. Before joining PAN, she was the Senate-confirmed Director of the US Office of Government Ethics from 2000-2003 and the Associate Counsel to the President in the White House Counsel's Office from 1998-2000. Ms. Rick began her federal service as a career attorney at the US Department of Education in 1989 and became the Assistant General Counsel for Ethics in 1993. Prior to her government service, Ms. Rick was an associate attorney at the law firm of Beveridge & Diamond. She received a Bachelor of Arts degree from Bard College and a Juris Doctor degree from the University of Michigan.

MICHAEL T. ROBERTS is founding Executive Director of the newly established Resnick Program for Food Law and Policy at UCLA School of Law. He is well versed in a broad range of legal and policy issues from farm to fork in local, national, and

global food supply systems. He has recently authored the first major treatise on food law, titled, *Food Law in the United States*, published by Cambridge University Press. He is also co-editor of *Food Law & Policy*, a new casebook to be published by Wolters Kluwer. He has also written several other chapters and articles on food law topics. Mr. Roberts is actively involved in the development of food law and policy. He has guest lectured on food-law subjects at various law schools in the U.S., Asia, and Europe. He is a Research Fellow for Renmin University School of Law's Center for Coordination and Innovation for Food Safety. He is an Adjunct Professor of Law for East China University of Science and Technology (Shanghai), where he lectures annually on food law topics. He also lectures frequently and is involved with the University of Tuscia, European Food Law Center (Viterbo, Italy). He is also an Adjunct Professor of Law at Michigan State University, where he teaches a distant education course on China food law. He serves on the advisory board for the World Food Law Institute and on the Editorial Board for MDPI Laws, an open access scholarly journal, which has addressed food law topics.

JODI SCHIPPER is Regulatory Counsel in the Office of Compliance at FDA's Center for Drug Evaluation and Research. She has previously focused on synthetic drug policy while working for Senator Conrad Burns (R-MT) and also at the White House's Office of National Drug Control Policy, where she served as Counselor to the Director. She obtained her undergraduate degree from Georgetown University and her law degree from The Catholic University of America's Columbus School of Law. She anticipates receiving her Master in Public Health degree from Harvard University's T.H. Chan School of Public Health next month. Ms. Schipper is licensed to practice law in Washington, DC, and also holds inactive memberships in Montana, California, and the State of Washington.

VALERIE B. SOLOMON is managing Counsel for Regulatory Affairs at RAI Services Company, a subsidiary of Reynolds American Inc. (RAI). Among other responsibilities, she counsels RAI and its operating companies on state, federal, and international regulatory compliance. Prior to joining RAI Services in 2010, Ms. Solomon was in private practice in Washington, DC, where she counseled clients in the food, medical device, and pharmaceutical industries on various regulatory, litigation, and policy matters. Ms. Solomon also previously served as Vice President for research at a healthcare-focused investment and advisory firm. Ms. Solomon received her BA in history from Yale University and her JD from Washington College of Law, American University.

KENNETH E. WARNER is the Avedis Donabedian Distinguished University Professor of Public Health and Professor of Health Management and Policy at the University of Michigan School of Public Health, where he has been on the faculty since 1972. He served as Dean of the School of Public Health from 2005-2010. An economist, Dr. Warner earned his A.B. degree summa cum laude from Dartmouth College in 1968 and MPhil and PhD degrees from Yale University in 1970 and 1974, respectively. Presented in over 200 professional publications, Dr. Warner's research has focused on economic and policy aspects of disease prevention and health promotion, with a special emphasis on tobacco and health. Dr. Warner served as the World Bank's representative to negotiations on the global treaty on tobacco control, the Framework Convention on Tobacco Control. He also served as the Senior Scientific Editor of the 25th anniversary Surgeon General's report on smoking and health, published in 1989. He has chaired the Editorial Advisory Board of the international journal Tobacco Control since the journal's inception in 1992. During 2004-05 he was President of the Society for Research on Nicotine and Tobacco. He consults with numerous governmental bodies and voluntary

organizations, and was a founding member of the Board of Directors of the American Legacy Foundation (now the Truth Initiative). He was also founding Director of the University of Michigan Tobacco Research Network. Dr. Warner has testified before the U.S. Senate and the House of Representatives.

JEFF WEISS serves as General Counsel and EVP of Government Affairs for NJOY, LLC. In 2017 NJOY, LLC acquired the assets of NJOY, Inc., a pioneer in the electronic nicotine delivery system (ENDS) market. NJOY's products are distributed in brick and mortar stores in all 50 U.S. states. Jeff has oversight responsibility for NJOY's legal and regulatory affairs, both in the U.S. and abroad. From 2012 to 2017, Jeff served as General Counsel for NJOY, Inc. and from July 2016 to February 2017 as its Interim President. Jeff's involvement with ENDS dates back to NJOY, Inc.'s history-making litigation with FDA (Sottera v. FDA), which established the legal foundation for the entire U.S. ENDS industry. In addition to his law degree, Jeff holds a Masters Degree in Biotechnology from Johns Hopkins and a Master of Laws in International Law from the Georgetown University Law Center.

PATRICIA J. ZETTLER is an associate professor of law and a faculty member of the Center for Law, Health & Society at the Georgia State University College of Law. Before joining Georgia State in 2015, she served as a fellow at the Center for Law and the Biosciences at Stanford Law School, and, before that, as an associate chief counsel in FDA's Office of the Chief Counsel. From 2016 to 2017, she served as a consultant to the National Academies of Sciences, Engineering, and Medicine's Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse. In addition to her legal background, Zettler has bioethics experience through work at the Program in Medical Ethics at the University of California San Francisco and at the Department of Bioethics at the National Institutes of Health. She received her undergraduate and law degrees from Stanford University, both with distinction.

ALLISON M. ZIEVE is Director of Public Citizen Litigation Group and General Counsel of Public Citizen, a non-profit consumer advocacy organization devoted to research, advocacy, and education on a wide range of public health and consumer safety issues. Allison's practice addresses food and drug law, consumer health and safety, the first amendment, access-to-courts issues, and open government. She has argued five cases before the U.S. Supreme Court and many more before federal courts of appeals. In addition to litigating, Allison serves as a board member of the Food and Drug Law Institute, a senior fellow of the Administrative Conference of the United States, and a member of the American Law Institute. She has taught courses as an adjunct professor at Georgetown University School of Law and American University's Washington College of Law. Allison is a graduate of Brown University and Yale Law School.